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09/889,901	07/24/2001	Larry Y. Yen	MCA-400 PC/U	3005

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EXAMINER

MENON, KRISHNAN S

ART UNIT	PAPER NUMBER
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1723

DATE MAILED: 04/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/889,901

Applicant(s)

YEN ET AL.

Examiner

Krishnan S Menon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-27 are pending.

Specification

The attempt to incorporate subject matter into this application by reference to 60/117,852 and 60/117,854 in page 6 is improper because they are provisional applications. Applicant is required to amend the specification with the corresponding patent or application publication numbers if/when published, or incorporate the essential material from these references into the specification, if not published or issued as patents.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 19, 20, and 22 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by, or in the alternative, under 35 U.S.C. 103(a) as obvious over EP 0 299 459 A2.

EP teaches an all perfluorinated thermoplastic hollow fiber membrane cartridge as in instant claims (see fig 5, page 4 lines 35-40, page 5 lines 36-49). Re method of making the cartridge, these claims are product by process, and "[E]ven though product-by-process claims are limited by and defined by the process, determination of

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patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re *Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Even though the reference teaches other thermoplastic materials as useful for making the cartridge (like polyethylene), the preferred material is all thermoplastic fluoropolymer (page 2 lines 32-39, page 4 lines 35-40, page 5 lines 43-48, working examples). The hollow fibers are made using a filler and pore-former, but such additives are completely extracted out leaving only thermoplastic fluoropolymer in the cartridge.

2. Claims 20, and 22 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by, or in the alternative, under 35 U.S.C. 103(a) as obvious over Niermeyer (US 5,695,702).

Niermeyer teaches a thermoplastic hollow fiber membrane cartridge as in instant claims. See fig 6, claims 8 and 10 and col 4 lines 45-50. Claim 10 of Niermeyer teaches thermoplastic fluoropolymer for the potting and claim 8 teaches PTFE for the hollow fibers, making it all fluoropolymers. Re method of making the cartridge, these claims are product by process, In re *Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-18, 21, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huang et al (US 5,284,584) in view of EP 0 299 459 A2 and Miyagi et al (US 5,114,508).

Claim 1: Please note that the claim language reads as if only the hollow fiber is of all thermoplastic perfluorinated resin. However, applicant's arguments imply that the hollow fiber and the potting resin are all perfluorinated thermoplastic, and the examiner assumes that that is the case. Applicant may want to re-word the claim to make it clearer.

Huang teaches a method of forming an all thermoplastic (col 23 lines 10-28, and col 13 lines 25-31), hollow fiber module (abstract; fig 4,5; col 11 lines 39-44) comprising the steps of:

contacting a plurality of hollow fiber membranes made from one or more thermoplastic resins with one or more molten thermoplastic potting resins to form a substantially parallel array of said membranes (see fig 1; col 4 lines 12-44),
said one or more potting resins being heated sufficiently above their peak melting point but at or below the peak melting point of the membranes such that they are applied to said membranes at a contact temperature which causes said one or more potting resins

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streams to flow around said hollow fiber membranes to form a bundle of hollow fiber membranes (col 11 lines 20-25; col 13 line 32- col 14 line 55)

cooling said bundle (col 14 lines 5-15, 44-48);

heating said bundle to a temperature below the peak melting point of the hollow fibers and above the peak melting point of the one or more potting resins for a period sufficient to form a fluid-tight seal between the one or more potting resins and the hollow fiber membranes (col 14 lines 48-55).

Re the element of the seal being "free of voids", see col 14 lines 40-55 and of Huang ref – eliminate gaps and voids. The process step in lines 48-55 teaches that the molten band, as it is laid on the fabric is solidified, and is melted by re-heating to make the tube sheet, which is fusing the layers of the winding together, or "filling the voids", as claimed.

What Huang does not teach is a method "consisting of" an all thermoplastic perfluorinated resin module. EP teaches TFE-co-PFAVE resin (perfluorinated thermoplastic) for hollow fiber modules (lines 35-40, page 4, examples). Miyagi teaches an all fluorinated resin filter by potting (or sealing) filters using perfluorinated thermoplastic resins (col 5 lines 43-55). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of EP and Miyagi in the teaching of Huang for obtaining hollow fiber modules with "excellent heat and chemical resistance" as taught by EP and Miyagi (see also Miyagi abstract).

Additional limitations of the instant claims are taught by Huang as follows:

Claim 2. The method of claim 1 wherein the peak melting point of the one or more potting resins is at least 5C below that of the hollow fiber membranes. (Huang: col 11 lines 20-25; Miyagi col 5 lines 43-55 – same materials as used by the applicant)

Claim 3. The method of claim 1 wherein the peak melting point of the one or more potting resins is at least 10 C below the peak melting point of the hollow fiber membranes, (Huang: col 11 lines 20-25; Miyagi col 5 lines 43-55)

Claim 4. The method of claim 1 wherein the one or more thermoplastic, perfluorinated resins of the hollow fiber membranes and the potting resins are selected from the group consisting of homopolymers, copolymers, blends of one or more homopolymers, blends of one or more copolymers and blends of one or more homopolymers and copolymers of perfluorinated resins (Huang: col 11 lines 39-45; Miyagi col 5 lines 43-55).

Claim 5. The method of claim 1 wherein the one or more thermoplastic, perfluorinated resins of the hollow fiber membranes and the potting resin are selected from the group consisting of (TFE-co-PFAVE) resins and blends thereof (EP: col 4 lines 35-40; Miyagi col 5 lines 43-55, col 6 lines 1-17).

Claim 6. The method of claim 1 wherein the bundle is heated to a temperature at or above the peak melting point of the one or more potting resins (Huang col 14 lines 2-48; Miyagi col 5 lines 43-55).

Claim 7: The method of claim I wherein the plurality of hollow fiber membranes is formed prior to contacting said membranes with said potting resins by forming said membranes together in a contiguous relation (fig 1; col 4 lines 15-20).

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Claim 8. The method of claim 1 wherein the array is formed prior to contacting said membranes with said potting resins by forming said membranes together in a spaced apart relation (fig 1; col 4 lines 15-20).

Claim 9. The method of claim 1 wherein the potting resin is a thin stream deposited in a defined zone near one end of said membrane array (fig 1).

Claim 10. The method of claim 1 further comprising the step of contacting a second thin stream of potting resin near an opposite end of said array of membranes (fig 1).

Claim 11: The method of claim 1 further comprising the steps of forming a substantially parallel array of said membranes and subsequently spirally winding said array about an axis which is substantially parallel to a longitudinal axis of said membrane array while simultaneously applying said potting resin to the array of membranes to form circular bundle of fibers having at least one potted end. (fig 1; col 4 lines 15-20).

Claim 12. The method of claim 11 further comprising the step of continuing to apply said potting resin after said circular bundle is formed to create a tube sheet of predetermined diameter about at least one end of said hollow fiber membranes. (col 14 lines 25-30; 56-65)

Claim 13. The method of claim 1 further comprising the step of cutting the at least one potted end of the bundle orthogonally to the longitudinal axis of said hollow fiber membranes to form said bundle with at least one flat end surface having exposed lumens (col 9 lines 1-6).

Claim 14. The method of claim 13 further comprising the step of mounting said bundle into a cartridge housing (col 9 lines 7-10).

Claim 15. The method of claim 14 wherein the bundle is mounted in said housing by fusion bonding (col 15 lines 4-8)

Claim 16: A. method of making a hollow fiber membrane cartridge comprising:

- a. forming a plurality of hollow fiber membranes formed of one or more thermoplastic resins into a substantially parallel arrangement wherein the fibers are arranged in parallel arrangement along a length of the fibers; then
- b. winding the plurality of hollow fibers about an axis which is substantially parallel to the length of the hollow fiber membranes so as to form a bundle having two bundle ends (fig 1; col 4 lines 11-44);
- c. simultaneously with step (b), extruding a molten stream of a thermoplastic resin having a peak melting point at least 5 C below the peak melting point of the hollow fiber membranes (Huang: col 11 lines 20-25; Miyagi col 5 lines 43-55) and having a melt flow index of 100 g/10 min (col 4 lines 25-31; Miyagi col 5 lines 43-55 – same materials). or greater and directing said resin onto at least one of the two bundle ends to thereby pot one or more ends in said resin (fig 1);
- d. cooling the bundle;
- e. heating the bundle at the one or more potted ends to a temperature at or above the peak melting point of the resin of the stream but below the peak melting point of the hollow fibers (col 14 lines 48-55); and

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f. exposing the lumen ends of the hollow fiber membranes at one or more potted bundle ends to communicate with the exterior of the bundle (see fig 6)

Huang does not teach specific thermoplastic resin as perfluorinated thermoplastic. EP teaches TFE-co-PFAVE resin for hollow fiber modules (lines 35-40, page 4, examples). Miyagi teaches an all fluorinated resin filter by potting (or sealing) filters using perfluorinated thermoplastic resins (col 5 lines 43-55). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of EP and Miyagi in the teaching of Huang for obtaining hollow fiber modules with "excellent heat and chemical resistance" as taught by EP and Miyagi (see also Miyagi abstract).

Re the limitation of "eliminate voids in said potted ends", see Huang col 14 lines 40-55. The process step in lines 48-55 teaches that the molten band, as it is laid on the fabric is solidified, and is melted by re-heating to make the tube sheet, which is fusing the layers of the winding together, or "filling the voids", as claimed

Claim 17. The method of claim 16 wherein both ends of the bundle are potted with the molten stream of the perfluorinated thermoplastic resin (fig 1) (Miyagi col 5 lines 43-55).

Claim 18. The method of claim 16 wherein both ends of the bundle are potted with the molten stream of the perfluorinated thermoplastic resin and wherein both ends of the bundle are exposed so that the lumen ends of the hollow fiber membranes can communicate with the exterior of the bundle (fig 1, col 9 lines 1-6; Miyagi col 5 lines 43-55).

Claim 21. The method of claim 16 further comprising the steps of:

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- g. inserting the bundle into a housing for the bundle having a first and second end and a cylindrical housing interior being suitably shaped to contain the membrane bundle, a first means for sealing the first end of the bundle to the interior of the housing adjacent its first end, a second means for sealing the second end of the bundle to the interior of the housing adjacent its second end, the housing having one or more means for dividing the bundle into at least two regions including a shell side space exterior to the portion of the bundle between the potted ends and a space including the lumens (fig 4,5,6); then
- h. applying a first end cap adjacent the first end of the housing to seal the first housing end; then
- i. applying a second end cap adjacent the second housing end so as to seal the second housing end; and
- j. providing a shell side access in the housing and at least one access in at least one of the first or second end caps (col 9 lines 7-40; col 15 lines 4-11).

Claim 23. A method according to claim 16 wherein the potting compound has melt flow Index of from about 100 to about 200 g/10 min (col 4 lines 25-30; Miyagi col 5 lines 43-55 – same materials).

4. Claims 24- 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huang et al (US 5,284,584) in view of EP 0 299 459 A2 and Miyagi (508) as in claims 1-18, 21 and 23 above, and further in view of Niermeyer (702).

Huang in view of EP does not teach forming one or more strips of perfluorinated thermoplastic resin over the array before winding. Niermeyer teaches forming one or

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more strip of the perfluorinated thermoplastic resin (claim 10) on the array before winding and then potting (col 6 line 24 – col 7 line 11; fig 4). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Niermeyer in the teaching of Huang in view of EP for easier assembly without forming the fabric of hollow fibers as taught by Huang in view of EP and Miyagi.

Re the element in claim 24, "free of voids", see Huang col 14 lines 40-55.

Response to Arguments

Applicant's arguments filed 10/17/03 have been fully considered but they are not persuasive.

Argument that the EP '459 reference does not teach 'all thermoplastic perfluorinated resin' because it uses various fillers in the fiber, even though the fillers are extracted. This argument lacks merit because the applicant's hollow fiber membrane is also made using a filler (solvent) for extrusion and pore formation, and then an extraction solvent to remove this filler, and therefore, introduces extractables that could contaminate the filtrate as in EP'459 reference. (Ref: applicant's incorporation by reference in the specification: 60/117,852; US 4,990,294). Also, insistence on this argument would be admission that the newly added element, 'consisting of all thermoplastic ...' is new matter and/or that there is insufficient disclosure in the specification to be enabling re how the hollow fibers are made with pure perfluorinated thermoplastic material, absolutely free of contaminants.

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Applicant's argument re the process claims 1-18, 21 and 23: Huang ref teaches fluoropolymers "including" PTFE in col 11 lines 37-45. The word "including" does not eliminate or preclude thermoplastic fluoropolymers, and definitely will not be "teaching away". Huang teaches thermoplastic polymers for his invention, as stated in the rejection (see col 13 lines 25-30 – all thermoplastic polymers). Secondary heating is taught in col 14 lines 50-55. Re the argument that Huang does not supply the deficiencies of EPO'459, EPO'459 is not the primary reference, Huang is the primary reference for the process claims. Huang teaches secondary heating as stated in the rejection. Claim reads applying molten resin to form the bundle of hollow fibers, cooling it and then heating the bundle a second time to melt the potting resin. Reference has the potting resin applied along the fibers of the fabric (fig 1, col 14 lines 48-55), and then the fabric wound to form the bundle, and then the potting resin melted again to complete the potting (form the tube-sheet). What Huang says is that the molten band could be allowed to solidify before the winding is complete, and there is nothing in the reference that prevents the molten resin from going into the fabric and around the fibers while it is being applied as shown in the figure.

Rest of the arguments are moot – new grounds for rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Krishnan Menon
Patent Examiner


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